

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MISSOURI  
CENTRAL DIVISION**

<b>EARL RINGO, et al.,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>vs.</b>	)	<b>No. 09-4095-CV-C-NKL</b>
	)	
<b>GEORGE A. LOMBARDI, et al.,</b>	)	
	)	
<b>Defendants.</b>	)	

**Additional Supplemental Suggestions in Support  
of Plaintiffs’ Motion for Summary Judgment and in Opposition to  
Defendants’ Motion for Summary Judgment**

During the teleconference of February 4, 2011, the Court mentioned the pendency of a Supreme Court case involving the preemptive effect of the Food, Drug and Cosmetic Act. That case has now been decided: *Pliva, Inc. v. Mensing*, — S. Ct. —, No. 09-993, 2011 WL 2472790 (U.S. Jun. 23, 2011). Its holding informs the dispositive question identified by the Court’s order of August 19, 2010: whether Defendants’ method of lethal injection “can consistently stand together with the CSA and FDCA.” ECF Doc. 138, at 11.

In *Pliva*, patients who were injured by a generic version of the drug Reglan sued the manufacturers under Minnesota and Louisiana tort law, arguing that the drug’s label did not sufficiently warn of the risk that long-term users might develop the neurological disorder tardive dyskinesia. *Id.* at \*4. The defendants successfully invoked the doctrine of preemption. The Food, Drug, and Cosmetic

Act requires a generic drug's label to be equivalent to the original drug's label. *Id.* at \*6. Therefore, even when new evidence surfaced about the risk of tardive dyskinesia, the pharmaceutical companies could not have changed their labels to warn of this danger without prior FDA approval of changed labels for *all* original *and* generic Reglan. *Id.* The Supreme Court thus found "conflict preemption," reasoning that it would have been "impossible" for the manufacturers to comply with both the FDCA and state tort law obligations. *Id.* at \*9. It was "impossible" for the defendants to comply with both state and federal law, the Court reasoned, even though the manufacturers could have theoretically urged the FDA to allow changes for all Reglan labels. *Id.* Preemption existed because, unlike manufacturers of "new drugs," generic manufacturers cannot "unilaterally" change their labels so as to obey the FDCA and state tort law at the same time. *Id.* at \*9-\*10. The court thereby distinguished its earlier ruling in *Wyeth v. Levine*, 555 U.S. 555, 573 (2009), which rejected a preemption defense by a "new drug" manufacturer. *Id.* at \*10, \*12.

Impossibility preemption exists in this case as in *Pliva*, and under the same statute. As Plaintiffs have earlier explained, it is impossible for Defendants to comply simultaneously with federal law and their written protocol and practices, the latter of which are considered "law" for purposes of preemption. *See Golden State Transit Corp. v. City of Los Angeles*, 475 U.S. 608, 614-15 & n.5 (1986) (preemption of city's ongoing practice of not renewing taxi franchises for

companies whose workers are on strike); *Verizon Maryland v. Public Service Comm'n of Maryland*, 535 U.S. 635, 645 (2002) (preemption of adjudicative order of state regulatory commission). First, Defendants' protocol assigns to non-medical personnel the task of performing an "IV push" of the controlled substance sodium thiopental, in order to suppress pain – and yet federal law requires that this drug be administered by a federally licensed practitioner. *See* Plaintiffs' SOF ¶¶ 26-29, 58-61; 21 U.S.C. § 822(a)(2) (no dispensing without registration); 21 U.S.C. § 802(10) (term "dispense" includes "administering of a controlled substance"). Second, Defendants expressly refuse to incorporate medical prescriptions into their method of lethal injection; indeed, the protocol *requires* the use of thiopental regardless of whether this choice accords with a medical practitioner's judgment, reflected in a valid and statutorily-required prescription, that it optimally reduces the risk of excruciating pain from the other two drugs. *See* Plaintiffs' Ex. 5 (Depo. of M3) (also Defendants' Ex. 2), at 39 ("There's other things that can be used that are better drugs, but they're not part of the protocol that is used now."); Plaintiffs' SOF ¶¶ 16, 17, 56, 57; 21 U.S.C. § 353(b)(1) (requiring prescription); 21 U.S.C. § 829(b) (same). It is impossible, then, for Defendants to comply with the FDCA and the CSA while adhering to their chosen means of lethal injection.

*Pliva* is also significant in its rejection of arguments made by the Defendants here. The dissent in *Pliva* argued, unsuccessfully, that "[t]he States

have traditionally regulated health and safety matters,” that Congress was surely aware of state tort litigation against drug manufacturers over the decades, and yet, that Congress has not expressly invalidated such state law. 2011 WL 2472790, at \*16 (Sotomayor, J., dissenting); *see also id.* at \*22 (“[T]he majority disregards our previous hesitance to infer congressional intent to effect such a sweeping change in traditional state-law remedies.”). Defendants contend likewise in this case. *See* Defendants’ Suggestion in Opposition to Plaintiffs’ Motion for Summary Judgment (ECF Doc. 242), at 17-19 (“[T]he intention of Congress to exercise control over the area traditionally left to the States must be unmistakably clear or it is presumed not to exist. . . .”); *id.* at 23-24 (citing *Wyeth*, and arguing, “It must be presumed that Congress did not intend the CSA and FDCA to preempt State law on carrying out the execution of State criminals, an area traditionally occupied by the States, and it also must be presumed that if Congress really viewed the purpose of the FDCA and CSA as including the regulation of executions it would have expressly said so in the decades that the United States and the Several States have carried out executions by lethal injection.”); Defendants’ Motion for Summary Judgment (ECF Doc. 213), at 18-20, 28.

Finally, it bears mention that *Pliva* spoke of preemption in terms of a “private” party’s ability to comply with both state and federal law. *Id.* at \*8-\*12. That language, of course, does not change the fact that preemption applies to state actors who violate federal statutory law – including, but not limited to, *Ex parte*

*Young* actions in which the federal law does not itself provide a right of action. *See, e.g., Golden State*, 475 U.S. at 614-16 (preemption of city's franchising practices); *Verizon*, 535 U.S. at 642, 647-48 (permitting *Ex parte Young* action to preempt enforcement of state board's order, even though Telecommunications Act did not expressly "confer jurisdiction" for such cases); *Planned Parenthood of Houston & Southeast Tex. v. Sanchez*, 403 F.3d 324, 331-334 (5th Cir. 2005); *Qwest Corp. v. City of Santa Fe*, 380 F.3d 1258, 1266 (10th Cir. 2004). *Pliva* happened to be a tort case against private companies, and obviously not an *Ex parte Young* suit. The Court's discussion about a "private" party's ability to comply with both state and federal law simply reflects the circumstances of the case. It does not call into question the well-established principle that preemption applies when a state-affiliated party enforces state law in manner that conflicts with federal law. Thus, *Pliva* both retains and strengthens this Court's ruling that Plaintiffs state a viable claim of preemption. *See* Order of Aug. 19, 2010 (ECF Doc. 138), at 11 (on motion for judgment on the pleadings); Order of Nov. 30, 2010 (ECF Doc. 167), at 4 (on motion to amend complaint).

WHEREFORE, for the foregoing reasons, Plaintiffs respectfully renew their requests that the Court grant Plaintiffs' motion for summary judgment, deny Defendants' motion for summary judgment, and enter appropriate equitable relief.

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 28th day of June, 2011, to Andrew W. Hassell, Michael J. Spillane, and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

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